

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---------------------------------------|---|------------------------------|
| SEPRACOR, INC. |) | <u>REDACTED</u> |
| |) | <u>PUBLIC VERSION</u> |
| Plaintiff, Counterclaim-Defendant, |) | |
| |) | |
| v. |) | C.A. No. 06-113 KAJ |
| |) | |
| DEY, L.P. AND DEY, INC. |) | |
| |) | |
| Defendants, Counterclaim-Plaintiffs.) |) | |

**DEY'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO STRIKE
PLAINTIFF'S CLAIM FOR WILLFUL INFRINGEMENT**

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Dated: December 1, 2006
175650.1

Defendants, Counterclaim-Plaintiffs Dey, L.P. and Dey, Inc. (collectively “Dey”) respectfully submit this reply memorandum in support of their Motion to Strike the Allegations Concerning Willful Infringement of Plaintiff, Counterclaim-Defendant, Sepracor, Inc. (“Sepracor”).

I. SEPRACOR’S ALLEGATIONS OF WILLFULNESS ARE INSUFFICIENT AS A MATTER OF LAW AND SHOULD BE STRICKEN

In *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004), the Federal Circuit made it clear that “the mere fact that a company had filed an ANDA application or certificate cannot support a finding of willful infringement for purposes of awarding attorney’s fees pursuant to 35 U.S.C. § 271(e)(4).” In its Answering Brief, Sepracor seeks to turn the Federal Circuit’s decision in *Glaxo* on its head by arguing that its allegations of willful infringement should be permitted because they “relate to Dey’s willfulness as it pertains to exceptional case under section 285.” (D.I. 74, Sepracor Answering Br. at 5.) However, as the Federal Circuit found “[w]hile a myriad of factual circumstances may give rise to a finding that a case is exceptional for purposes of 35 U.S.C. § 285, this court has limited what types of conduct may give rise to an award of attorney’s fees for purposes of Section 271(e)(4).” *Glaxo*, at 1350. Sepracor cannot be awarded attorneys fees for willful infringement based upon allegations relating to the filing of an ANDA simply because it characterizes those allegations as “willfulness for purposes of an exceptional case.” (D.I. 74, Sepracor Answering Br. at 4); *Boehringer Ingelheim Intern. GmbH. et al. v. Barr Labs., Inc.*, No. 05-700, 2006 WL 1876918, at *2 (D. Del. Jul. 6, 2006) (Jordan, J.) (a finding of an exceptional case cannot be based solely on allegations that the filing of an ANDA with a Paragraph IV certification constitutes willful infringement).

In its Complaint, Sepracor’s request for attorney’s fees under § 285 is related solely to its allegations that the factual and legal basis for Dey’s statement of invalidity in its Paragraph IV

certification is “devoid of an objective good faith basis.” (D.I. 1, Complaint, ¶25.) Sepracor further avers that this alleged artificial act of infringement “is, has been, and continues to be willful and deliberate.” (D.I. 1, Complaint, ¶26.) However, Sepracor’s allegations all relate to Dey’s filing of its ANDA and accompanying Paragraph IV certification, which the Federal Circuit has held is insufficient to justify a finding of willful infringement. *Glaxo*, at 1350. Accordingly, even if taken as admitted, Sepracor’s allegations are insufficient as a matter of law to support a finding of willful infringement, and therefore must be stricken.

II. SEPRACOR’S REQUEST FOR A FINDING OF EXCEPTIONAL CASE IS BASED SOLELY ON ITS ALLEGATIONS OF WILLFUL INFRINGEMENT

In its prayer for relief, Sepracor requests “[a] judgment that Dey, L.P.’s and Dey Inc.’s infringement of the Sepracor Patents was and is willful and that Sepracor is entitled to its reasonable attorneys’ fees pursuant to 35 U.S.C. ¶285.” (D.I. 1, Complaint, ¶D.) Sepracor makes no allegations to support its request for a finding of exceptional case under § 285, other than those relating to willful infringement based upon Dey’s filing its ANDA along with its accompanying Paragraph IV certification. A finding of exceptional case cannot be based solely on allegations that an ANDA filing and accompanying Paragraph IV certification constitutes willful infringement. *Boehringer*, at *2. Sepracor cannot bootstrap its allegations of willful infringement on its request for a finding of exceptional case.

III. THIS MOTION WAS NECESSARY BECAUSE SEPRACOR RESCINDED ITS PROPOSAL TO WITHDRAW ITS ALLEGATIONS OF WILLFULNESS

Sepracor argues that Dey’s motion to strike “is the epitome of a wasteful expenditure of time and money because Dey filed this motion rather than providing productive comments or revisions to Sepracor’s draft proposed stipulation [to stay discovery].” (D.I. 74, Sepracor Answering Br. at 7.) Sepracor’s argument has no basis in fact.

In August 2006, Sepracor's counsel provided Dey's counsel with a copy of this Court's July 2006 decision in *Boehringer*, and proposed over the telephone that the parties enter into a joint stipulation to withdraw the allegations of willfulness without prejudice. (See D.I. 74, Sepracor Answering Br., Exhibit A.) Dey agreed to Sepracor's proposal that Sepracor withdraw its claim of willful infringement without prejudice. Sepracor's claim that it never proposed withdrawing its claim for willful infringement and instead only proposed a stay of discovery is belied by its August 28, 2006 Interrogatory Responses. In response to Dey's Interrogatory No. 13, which requested the "factual and legal basis for the allegations in the Complaint that Dey, Inc. and/or Dey, L.P.'s infringement of the patents-in-suit is willful,"

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Having heard nothing more from Sepracor with respect to its proposal to stipulate to withdrawing its allegations of willful infringement, on September 25, 2006, Dey's counsel sent Sepracor's counsel an e-mail inquiring as to the status of Sepracor's stipulation. (Exhibit 2.) Sepracor's counsel never responded. On October 20, 2006,

REDACTED

Sepracor had raised the issue of a stay.

In a letter dated October 27, 2006, Dey responded with surprise at Sepracor's change in position, and stated that it had never agreed to such a stipulation. (Exhibit 4, at 1.) As shown by Dey's October 25, 2006 letter to Sepracor, Dey held back filing a motion to strike Sepracor's

willfulness claims, based on its understanding that a joint stipulation withdrawing the allegations of willful infringement would be filed. (Exhibit 5.) On October 26, Sepracor responded and enclosed the draft proposed stipulation “it had been working on.” (See D.I. 74, Sepracor Answering Br., Exhibits B and C.) Contrary to Sepracor’s allegation that Dey never responded to Sepracor’s proposed stipulation, Dey responded the very next day stating that the stipulation to stay discovery was not acceptable and that Dey would file a motion to strike if a stipulation withdrawing the allegations of willfulness was not filed. (See Exhibit 4, at 3.) Following the discovery conference call with this Court, Dey once again requested that Sepracor fully respond to its interrogatories. With respect to Interrogatory No. 13 Dey stated:

Please send me a draft stipulation withdrawing Sepracor’s baseless allegation of willful infringement by 5 PM on Monday. If Sepracor is unwilling to file such a stipulation, please provide me with a time on Monday, November 6 for the parties to have a meet and confer teleconference on Dey’s intention to file a motion to strike. I am available for such a conference anytime on November 6 from 7:30 AM to 5:30 PM.

(Exhibit 6, at 2.) Dey received no response from Sepracor and filed its Motion to Strike on November 7.

Dey strongly contests any inference made in Sepracor’s Answering Brief that Dey simply filed a motion to strike without considering Sepracor’s draft. Rather, on several occasions, Dey informed Sepracor that it would be forced to file a motion to strike if Sepracor did not file a stipulation to withdraw its allegations of willful infringement as the parties had previously discussed. (See Exhibits 4, 5 and 6.) Any waste of resources is the result of Sepracor’s failure to timely inform Dey it had decided not to file the joint stipulation to withdraw its allegations of willful infringement without prejudice Sepracor itself had proposed.

IV. JUDICIAL EFFICIENCY WEIGHS IN FAVOR OF THIS COURT EXERCISING ITS DISCRETION TO GRANT THIS MOTION

Sepracor argues that Dey's motion should be denied as procedurally untimely because Dey did not make this motion until after it filed its Amended Answer and Counterclaims on October 23, 2006. However, it was not until October 23, 2006¹ that Dey's counsel first became aware that Sepracor was considering not filing the stipulation to withdraw the willfulness allegations. Rather than simply file the motion to strike that day, Dey's counsel spent the next few days trying to confirm that Sepracor had indeed decided not to file the stipulation as the parties had previously discussed. (See Exhibits 4 and 5.) The motion to strike was filed soon after it became clear that Sepracor was no longer interested in the stipulation Sepracor had proposed two months earlier. Dey's motion was filed after its Amended Answer and Counterclaims because Dey thought the parties were going to file a joint stipulation to withdraw the willfulness allegations, rendering the motion unnecessary. (See Exhibits 4 and 5.)

This Court has the discretion to hear a motion to strike brought under Fed. R. Civ. P. 12(f) even if untimely. *Sheridan v. E.I. duPont de Nemours and Co.*, No. 93-46, 1994 WL 468711, at *11 (D. Del. Mar. 28, 1994) (holding that Rule 12(f) permits a district court on its own initiative to entertain a motion to strike, and that the Court has the discretion to hear untimely motions). It was not until after Dey filed its Amended Answer and Counterclaims that it became clear it would be necessary for Dey to file a motion to strike. It is in the interests of justice to narrow the issues to be litigated. Indeed, that is the purpose of Fed. R. Civ. P. 12(f). *See Del. Healthcare, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1291 (D. Del. 1995). To deny Dey's motion because it was untimely would discourage attempts by litigating parties to narrow the issues before seeking court involvement. Judicial efficiency would not be served by such a result.

¹ Sepracor sent its Friday, October 20, 2006 (Exhibit 3) letter via email after close of business. It was not retrieved and reviewed until Monday, October 23, 2006.

V. CONCLUSION

For the reasons stated above, Dey respectfully requests this Court grant its Motion to Strike Sepracor's Allegations Concerning Willful Infringement.

ASHBY & GEDDES

/s/ Tiffany Geyer Lydon

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Dated: December 1, 2006
175650.1

EXHIBIT 1

REDACTED

EXHIBIT 2

From: Leff, Elizabeth
Sent: Monday, September 25, 2006 2:29 PM
To: 'Dadio, Susan'
Cc: 540013-502
Subject: Sepracor v Dey

Dear Susan:

Some time ago, you indicated that Sepracor would withdraw its allegations of willfulness without prejudice. I have not seen any stipulations or orders to effect the withdrawal of the willfulness allegations. Please let me know if and when Sepracor intends to withdraw these allegations.

Very truly yours,
Elizabeth Leff

Elizabeth A. Leff, Esq.
Frommer Lawrence & Haug LLP
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Tel: 202-292-1530

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EXHIBIT 3

REDACTED

EXHIBIT 4



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October 27, 2006

Elizabeth A. Leff
ELeff@flhlaw.com

VIA EMAIL

Susan Dadio
Buchanan Ingersoll & Rooney PC
1737 King Street, Suite 500
Alexandria, VA 22314-2727

Re: Sepracor Inc. v. Dey, L.P. and Dey, Inc.
Civil Action No. 06-113 KAJ

Dear Susan:

I am taken aback by your letter of October 26, 2006, which fails to accurately recount the facts.

First, I never "indicated that Dey wanted a forty-five to sixty day extension on the due date for amending the pleadings in exchange for any agreement concerning [Sepracor's voluntary withdrawal of its allegation of] Dey's willful infringement" (emphasis added.) There was never any connection between the two. In August, you called me to state that Sepracor would like to withdraw its allegations of willful infringement without prejudice as a result of Judge Jordan's decision in Boehringer Ingelheim International GMBH and Boehringer Ingelheim Pharmaceutical, Inc v. Barr Laboratories, Inc., et al CV-05-700-KAJ, dated July 6, 2006. This discussion was initiated by Sepracor, occurred weeks prior to Dey's request for an extension of the time to file amended pleadings, and was completely unrelated.

Second, you and I never discussed the filing of a stipulation to stay discovery. That the parties were discussing a stipulation for withdrawal of Sepracor's willfulness allegations, not a stay of discovery on the issue is illustrated by Sepracor's response to Dey's Interrogatory No. 13 requesting the basis for the willfulness allegations. Sepracor responded:

Sepracor objects to this Interrogatory because the parties are discussing Sepracor's withdrawal, without prejudice, of its claim for willfulness and, thus, this Interrogatory seeks information that may be neither relevant nor reasonably calculated to lead to admissible evidence.

SEPRACOR INC.'S OBJECTIONS AND RESPONSES TO DEFENDANTS' FIRST SET OF INTERROGATORIES at pp. 25-26.

Third, I never stated that I "'needed to serve requests for admissions' on Sepracor to obtain a 'good faith basis' to add a claim of inequitable conduct" (emphasis added). I stated that Dey wanted to serve requests for admission to aid it in determining whether a good faith basis existed for a defense and counterclaim of inequitable conduct. Dey did not simply make boilerplate

Susan Dadio
 October 27, 2006
 Page 2

inequitable conduct allegations in its initial complaint. It sought to obtain additional information prior to making such allegations. I also told you that if you did not stipulate to the extension, we would file a motion to amend at the appropriate time. Inequitable conduct claims, which are often uncovered during discovery, are frequently added in patent cases long after the deadline for amending pleadings has passed. I pointed out that Federal Rule of Civil Procedure 15(a) and United States Supreme Court case law supports freely granting leave to amend where there would be no prejudice. Since discovery had just begun and you had notice that Dey was considering amending its answer and counterclaims to include allegations of inequitable conduct, I was doubtful that you could successfully argue Sepracor was prejudiced by amendment.

Fourth, your insinuation that I misled you when I requested a forty-five day extension of the deadline for amending by telling you I had not drafted the requests for admission and then ambushed you by serving them the next evening also is inconsistent with the facts. When we spoke on the phone, I told you Dey needed forty-five days because Sepracor would have thirty days to respond and that would leave Dey with two weeks to draft the requests, consider Sepracor's responses and draft and file any additional defenses and counterclaims. I candidly told you that I only anticipated having a few requests to admit, that they would relate to issues of inequitable conduct, and that because I had not drafted them yet, I was not prepared to characterize them with any more particularity. The following day, Dey served its six requests to admit all related to Sepracor's knowledge of a single piece of prior art. Sepracor was hardly ambushed, and took the full thirty days to respond to these requests.

Fifth, Dey did not serve you with notices of deposition. Dey served you with notices that it was serving third party subpoenas under Federal Rule of Civil Procedure 45. As you are well aware, these third party subpoenas were born out of Dey's complete frustration at Sepracor's continual delays in producing documents. As I stated in response to your letter of September 15 requesting a meet and confer on Sepracor's request that Dey withdraw its subpoenas, "third party subpoenas are necessary at this juncture, in part because of Sepracor's delay in producing documents." LETTER FROM ELIZABETH A. LEFF TO SUSAN DADIO DATED SEPTEMBER 18, 2006. That the notices of subpoena were served the same day as the requests to admit was pure happenstance.

Sixth, you are wrong about the conversation in which bifurcation was raised. The issue was mentioned in the context of Sepracor's offer to enter a stipulation withdrawing its willfulness allegations without prejudice. I recall telling you in an offhand way that in the past I have bifurcated willfulness issues, but that there was no need in light of Sepracor's desire to stipulate to the withdrawal of its willfulness allegation. This comment hardly constituted an offer to bifurcate in this litigation.

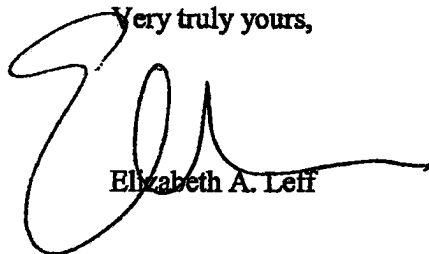
Finally, Sepracor has not raised any allegations of willfulness against Dey in the recently filed action (06-604) involving the concentrated form of levalbuterol. These actions involve similar subject matter as they both involve Dey's filing of ANDA to market generic version of Sepracor's Xopenex levalbuterol products. If Sepracor had a sufficient basis for its allegations of willfulness in this case, surely it would have had the same basis for making allegations of

Susan Dadio
October 27, 2006
Page 3

willfulness in that case. The fact that no allegations of willfulness were made in that case speaks volumes.

In view of these actual facts and the state of the law, we trust that Sepracor will withdraw its allegations of willfulness without prejudice. If Sepracor refuses to do so, Dey will be forced to file a motion to strike them.

Very truly yours,

A handwritten signature in black ink, appearing to be 'EL', with a long horizontal flourish extending to the right.

Elizabeth A. Leff

EAL/yhw

EXHIBIT 5



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October 25, 2006

Elizabeth A. Leff
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VIA EMAIL

Susan Dadio
Buchanan Ingersoll & Rooney PC
1737 King Street, Suite 500
Alexandria, VA 22314-2727

Re: Sepracor v. Dey; Our Reference No. 540013-502

Dear Susan:

In August you told me Sepracor wanted to enter into a stipulation to withdraw its allegations of willful infringement without prejudice and asked if Dey would agree. The basis for the withdrawal was an order in Boehringer Ingelheim International GMBH and Boehringer Ingelheim Pharmaceutical, Inc v. Barr Laboratories, Inc., et al CV-05-700-KAJ, dated July 6, 2006, in which Judge Jordan held that the filing of an ANDA with a paragraph IV certification cannot support an allegation of willful infringement. A copy is attached for your convenience. Dey agreed to the stipulation which Sepracor was to draft.

This is reflected in Sepracor's response to Dey's Interrogatory No. 13 requesting the basis for the allegation of willful infringement. Sepracor responded that "the parties are discussing Sepracor's withdrawal, without prejudice, of its claim for willfulness."

In your letter of October 20, you state "Dey's willfulness is a basis for exceptional case," and that you are "working on a draft proposal for joint stipulation, without prejudice, to stay discovery for exceptional case until such time as there is a prevailing party." Dey never agreed to a stipulation to stay discovery. Indeed, Dey has not filed a motion to strike the allegation of willfulness based upon the parties' agreement to file a stipulation withdrawing the allegation of willfulness. Please let me know 5 p.m. on Friday, October 27, 2006 whether, as it appears from your October 20 letter, Sepracor is breaking its agreement and no longer intends to file a stipulation to withdraw its allegation of willfulness without prejudice. If we do not receive a draft stipulation by that time, Dey will file a motion to strike.

Very truly yours,

A handwritten signature in black ink, appearing to be "Elizabeth A. Leff".

Elizabeth A. Leff

//yhw

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---------------------------------|---|-----------------------------|
| BOEHRINGER INGELHEIM |) | |
| INTERNATIONAL GMBH and |) | |
| BOEHRINGER INGELHEIM |) | |
| PHARMACEUTICAL, INC., |) | |
| |) | |
| Plaintiffs and |) | |
| Counterclaim Defendants, |) | |
| |) | |
| v. |) | Civil Action No. 05-700-KAJ |
| |) | (Consolidated) |
| |) | |
| BARR LABORATORIES, INC., et al. |) | |
| |) | |
| Defendants and |) | |
| Counterclaim Plaintiffs. |) | |

MEMORANDUM ORDER

Introduction

Before me is a Motion for Reconsideration (Docket Item ["D.I."] 39; the "Motion")¹ filed by defendant Mylan Pharmaceuticals Inc. ("Mylan") with respect to my previous ruling denying without prejudice Mylan's Motion to Strike Plaintiffs' Allegations Concerning Willful Infringement and to Bar All Discovery Relating Thereto (D.I. 8 in 05-854-KAJ; the "Motion to Strike"). For the reasons that follow, the Motion is treated as a renewal of the Motion to Strike, in which co-defendants Barr Laboratories, Inc. and Barr Pharmaceuticals Inc. (collectively "Barr") are deemed to join (see D.I. 55 at n. 1 ("Should the Court grant Mylan's motion, Barr will renew without delay its motion to

¹By order dated January 31, 2006, Civil Actions 05-700-KAJ and 05-854-KAJ were consolidated. (D.I. 33 in 05-700-KAJ.) Unless otherwise noted, citations to docket entries are to the docket in Civil Action No. 05-700-KAJ.

strike Boehringer's willfulness allegations.")), and is hereby granted to the extent described herein.

Background

This is a patent infringement case in which the plaintiffs, Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceutical Inc. (collectively "Boehringer"), assert that Mylan and Barr have infringed certain United States Patents owned by Boehringer. (See D.I. 1 at ¶¶ 18, 23.)² More specifically, Boehringer alleges that Barr has infringed Boehringer's U.S. Patents No. 4,886,812 (the "'812 patent") and No. 4,843,086 (the "'086 patent") by filing abbreviated new drug applications ("ANDAs") with the FDA, in an effort to market generic versions of drugs covered by those Boehringer patents. (*Id.* at ¶¶ 11-16, 18, 23.) Boehringer alleges essentially the same thing against Mylan with respect to the '812 patent. (D.I. 1 in 05-854-KAJ.) According to Boehringer, the defendants' infringement is willful (*Id.* at ¶¶ 20, 25), and Boehringer therefore seeks, among other things, a declaration that this is an exceptional case warranting the imposition of Boehringer's attorneys' fees on the defendants. (*Id.* at *ad damnum* ¶¶ B. and E.) Both Mylan and Barr sought to strike the allegations of willfulness. (D.I. 9; D.I. 8 in 05-854-KAJ.) I denied those motions on January 27, 2006.

Standard of Review

"Motions for reconsideration are to correct manifest errors of law or fact or to present newly discovered evidence." *Pell v. E.I. DuPont De Nemours & Co., Inc.*, 231

²The allegations recited herein are effectively the same in the Amended Complaint filed against Barr. (See D.I. 7.)

F.R.D. 186, 188 (D.Del. 2005). The party seeking reconsideration must show "at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion ...; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Cafe v. Quinteros*, 176 F.3d 669, 677 (3d Cir.1999).

Mylan has shown none of the applicable foundations for the granting of a motion for reconsideration. However, when I denied Mylan's Motion to Strike in the first instance, I expressly stated that the denial was "without prejudice" (1/27/06 Tr. at 11; see also D.I. 32),³ since I viewed the motions as "premature because I don't know what besides the filing of an ANDA might be in the mix here." (1/27/06 Tr. at 11.) The submissions of the parties have made it sufficiently clear to me that no other basis exists for the assertion of willfulness besides the defendants' filing of ANDAs and so I will accept the Motion as a renewed motion to strike on behalf of all of the defendants, which was expressly contemplated by my earlier ruling, rather than as a motion to reconsider the first denial.

Discussion

Since the decision by the United States Court of Appeals for the Federal Circuit in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), defendants in patent cases based on ANDA filings have regularly sought to dismiss charges of willfulness. They, like Mylan and Barr in this case, base their arguments on the *Glaxo* court's comment that "the mere filing of an ANDA cannot constitute grounds for a willful

³References to "1/27/06 Tr." are to the transcript of the January 27, 2006 teleconference in this case.

infringement determination." *Id.* at 1349. The district courts have split on the issue. See *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 444-45 (D.N.J. 2006) (collecting cases).

The more recent and growing weight of authority however, seems to be that an ANDA filing and accompanying paragraph IV certification⁴ cannot support a charge of willful infringement. See, e.g., *UCB Societe Anonyme v. Mylan Labs., Inc.*, No. 1:04-CV683-WSD, 2006 WL 486895, at *2 (N.D. Ga. Feb. 28, 2006) ("Applying *Glaxo* ..., [plaintiffs'] allegations cannot support a claim of willful infringement."); *Celgene*, 412 F. Supp. 2d at 445 ("The *Glaxo* case makes clear that the Hatch-Waxman Act exists ... to permit the matter [of infringement] to be decided before the drug goes to market and an actual, rather than artificial, act of infringement occurs."); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 409 F.Supp.2d 722, 729 (E.D. Va. 2006) ("[T]he fact that the appellate court in *Glaxo* emphasizes that the purpose of the ANDA process is to create an 'artificial' act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement."). That includes recent decisions from this court. See *Item Dev. AB v. Sicor Inc.*, No. Civ. 05-336-SLR, 2006 WL 891032, at *2 (D. Del. Mar. 31, 2006) (because the filing of an ANDA and paragraph IV certification by defendant "cannot support a claim of willful infringement, plaintiffs' complaint fails to state a claim on that basis."); *Allergan, Inc. v. Alcon, Inc.*, No. 04-968, 2005 WL 3971927, at *2 (D. Del. July 25, 2005) ("As the

⁴A paragraph IV certification is a submission made with an ANDA filing, by which a generic drug manufacturer asserts that a patent on a previously FDA-approved drug is invalid or will not be infringed by the proposed generic drug. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is 'exceptional' can be based on meritless filings combined with litigation misconduct, but a finding of willful infringement cannot."⁵

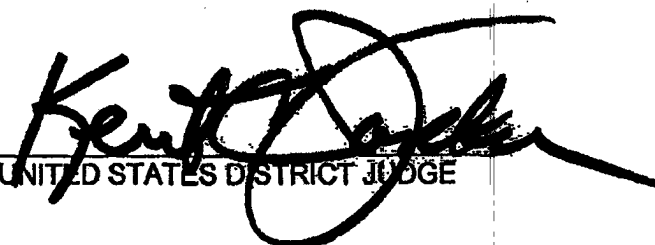
In light of that authority, which is persuasive, the plaintiffs' willfulness claims cannot stand and the motion to strike those claims will be granted. This does not, however, eliminate the question of whether there may, at some point, be occasion to find that this is an exceptional case. See *Item Dev.*, 2006 WL 891032, at *2 ("As the Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is 'exceptional' can be based on meritless filings combined with litigation misconduct, although a finding of willful infringement cannot.") (citing *Glaxo*, 376 F.3d at 1350-51); *Allergan*, 2005 WL 3971927, at *2 ("[T]he court will not foreclose Allergan from, at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case for which the court should award attorney's fees."). That decision must wait, since the issue may be determined, at least in part, on the conduct of the parties during the litigation of the case. Because it may also be unnecessary to ever decide the issue, the costs associated with discovery on it should be postponed.

Conclusion

Accordingly, based on the foregoing reasons and authorities, it is hereby ORDERED that the Motion (D.I. 39), treated as a renewed Motion to Strike in which Barr joins, is hereby GRANTED to the extent described herein; it is further ORDERED

⁵I have had occasion to issue an oral ruling to that effect as well. *In re '318 Patent Infringement Lit.*, C.A. No. 05-356-KAJ (D. Del. Mar. 3, 2006) (hearing transcript at 4-7).

that all discovery associated with whether this is an "exceptional case" within the meaning of 35 U.S.C. § 285 is stayed.


UNITED STATES DISTRICT JUDGE

July 6, 2006
Wilmington, Delaware

EXHIBIT 6



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Re: *Sepracor Inc. v. Dey, L.P. and Dey, Inc.*
Civil Action No. 06-113-KAJ

Dear Susan:

This letter is in response to your letter of October 20 and is written in light of the discovery dispute teleconference the parties had with Judge Jordan yesterday.

In my letter of September 26, we had requested that you identify the definitions that Sepracor used for the terms R(-) isomer and S(+) isomer when responding to Dey's first set of interrogatories. In your letter of October 20 you stated "Sepracor utilized definitions for such terms in accordance with at least the patents-in-suit." This is essentially a non-answer. Once again, please provide us with the definitions Sepracor used in responding to Dey's first set of interrogatories.

With respect to Sepracor's overly broad and unduly burdensome objections to Interrogatory Nos. 5, 6, 8, 9, 10 and 16 please confirm that Sepracor will identify "'all' 'each' and 'each and every' piece of information and/or individual or entity" Sepracor is aware of or has knowledge of. If Sepracor is holding back information on the basis of its overly broad and unduly burdensome objections, please provide us with the criteria Sepracor is using to determine who and/or what to identify.

Your response to Dey's concerns relating to privilege and the work product doctrine is unclear. Please explain what you mean by the statement "Sepracor has provided Dey with the information that it is entitled to receive" and confirm that Sepracor is not withholding factual information simply on the basis that it was relayed to an attorney.

INTERROGATORY NO. 2:

As reiterated during yesterday's teleconference with Judge Jordan, Dey's request that Sepracor "describe in full detail how each element of each asserted claim should be construed" requires that Sepracor provide the ordinary and customary meaning Sepracor attaches each element.

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Please confirm that Sepracor will supplement its response to Interrogatory No. 2 to include the ordinary and customary meaning Sepracor attaches to each asserted claim element.

INTERROGATORY NO. 3:

As Judge Jordan made clear during the teleconference, eight months has passed since Sepracor filed this action and Dey is entitled to know the basis for Sepracor's allegations of infringement. Please confirm that Sepracor will supplement its response to this interrogatory to include a claim chart which identifies Sepracor's infringement contentions.

INTERROGATORY NO. 4:

In your October 20 letter you refuse to provide the requested information concerning the conception, development and reduction to practice of the claimed inventions. You justify this refusal by stating that Dey has not asserted any art that is not more than one year prior to the filing of Sepracor's earliest filing date. This is plainly not the case as Dey has identified GB Patent No. 1,200,886, the complete specification of which was published in August, 1970, almost 20 years prior to the earliest possible filing date of the asserted patents. Please confirm that Sepracor will supplement its responses to provide the information requested in Interrogatory No. 4.

INTERROGATORY NOS. 5, 6, 7, 8, AND 9:

As explained in more detail in my letter of September 27, Sepracor has improperly invoked Rule 33(d) in response to these interrogatories. Please confirm that Sepracor will withdraw its reliance on Rule 33(d) and will provide the requested information.

INTERROGATORY NO. 8:

Dey confirms it was not trying to alter the terms of the Protective Order. Please confirm that to the extent any relevant documents have not been identified in Sepracor's interrogatory responses on the basis of a confidentially obligation or a protective order, that Sepracor will provide the information required in Paragraph 21 of the Protective Order in its interrogatory response.

INTERROGATORY NO. 13:

Please send me a draft stipulation withdrawing Sepracor's baseless allegation of willful infringement by 5 PM on Monday. If Sepracor is unwilling to file such a stipulation, please provide me with a time on Monday, November 6 for the parties to have a meet and confer teleconference on Dey's intention to file a motion to strike. I am available for such a conference anytime on November 6 from 7:30 AM to 5:30 PM.

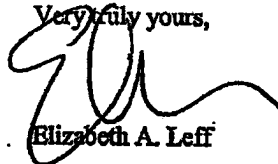
INTERROGATORY NOS. 14:

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Dey reiterates its request that Sepracor provide an element by element comparison of how one using each of the Sepracor products Sepracor has identified as falling within the scope of the asserted claims would infringe each claim. As you are aware, any assertion of commercial success Sepracor may make based upon the identified products requires Sepracor to show a link between the allegedly successful product and the patent claims. Please confirm that Sepracor will provide all of the information requested in Interrogatory No. 14.

Dey first served these interrogations three and a half months ago. Sepracor has had plenty of time to respond. Accordingly, we request Sepracor provide supplemental responses to Dey's interrogatories which include all the information requested in this letter by 5 PM Friday, November 10.

Very truly yours,

A handwritten signature in black ink, appearing to be "Elizabeth A. Leff", written over a horizontal line.

Elizabeth A. Leff